

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET NO. P30835DIV2C4	PREDECESSOR SERIAL NO. 10/044,848
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use several sheets if necessary)</i>		APPLICANTS Pathak et al.	
		PREDECESSOR FILING DATE January 11, 2002	PREDECESSOR GROUP 1615

## U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	AA	4,009,196	1977	Kurozumi et al.			
	AB	4,902,801	1990	Faruk et al.			
	AC	4,861,893	1989	Barrett			
	AD	5,039,803	1991	Smith et al.			
	AE	4,721,723	1988	Barnes et al.			
	AF	5,776,969	1998	James			

## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	BA	WO 92/09281	1992	WIPO				
	BB	EP A 0269 303	1988	EPO				
	BC	EP A 223 403	1987	EPO				
	BD	EP A 0 188 081	1986	EPO				
	BE	WO 93/22284	1993	WIPO				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CA	FDA FOIA Materials, June 1993
EXAMINER	DATE CONSIDERED

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## U.S. PATENT DOCUMENTS

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	AG	6,113,944	09/2000	Pathak, et al.			
	AH	4,007,196	02/1977	Christensen, et al.			
	AI	4,745,122	05/1988	Lassen, et al.			
	AJ	5,047,246	09/1991	Gallian, et al.			
	AK	4,804,669	02/1989	Lassen, et al.			
	AL	5,071,854	12/1991	Tyers, et al.			
	AM	5,229,407	07/1993	Coates, et al.			
	AN	6,077,535	06/2000	Tiongson, et al.			
	AO	5,340,810	08/1994	Clitherow, et al.			

## FOREIGN PATENT DOCUMENTS

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							Yes	No

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CFFF	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Order Dated December 2, 2002.
CFFG	Remington's Pharmaceutical Sciences, 18 <sup>th</sup> Edition, Mack Publishing Company (1990) pp. 1633-1658.
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**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	CB	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Complaint dated November 2000
	CC	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Defendant's Answer to Plaintiffs' Complaint dated November 2000
	CD	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Defendant Synthon BV's Answer to Plaintiffs' Complaint dated December 2000
	CE	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Plaintiffs' Reply to Defendant's Counterclaims dated December 2000
	CF	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Plaintiffs' Reply to Defendant's Counterclaims dated December 2000
	CG	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Plaintiffs' Amended Reply to Defendant's Counterclaims dated December 2000
	CH	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Defendant's Responses to Plaintiffs' First Set of Requests for Admissions (Nos. 1-7) dated April 2001
	CI	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Defendant's Response to Plaintiffs' First Set of Interrogatories (Nos. 1-8) dated April 2001
	CJ	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Joint Stipulated Protective Order Pursuant to Rule 26(c) dated May 2001
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	CK	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Defendant Synthon Pharmaceuticals Ltd.'s Motion and Supporting Memorandum for Leave to File an Amended Answer to Plaintiffs' Complaint and Counterclaims dated August 2001
	CL	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Plaintiffs' Response to Defendant's Motion for Leave to File an Amended Answer to Plaintiffs' Complaint and Counterclaims dated August 2001
	CM	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Plaintiffs' Reply to Amended Affirmative Defenses and Counterclaims Set Forth in "Defendant Synthon Pharmaceuticals, Ltd.'s Amended Answer to Plaintiffs' Complaint and Counterclaims" dated October 2001
	CN	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Defendants' Responses to Plaintiffs' Second Set of Requests for Admissions (Nos. 8-14) dated August 2001
	CO	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Order Granted September 2001
	CP	Civil Action No. 100CV01179, U.S. District Court for Middle District of North Carolina – Defendants' Amended Responses to Plaintiffs' Second Set of Requests for Admissions (Nos. 8-14) dated August 2001
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CS	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Torpharm's Motion for Summary Judgment of Invalidity of Claims 1 and 2 of U.S. Patent No. 6,113,944
CT	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Torpharm's Memorandum of Law In Support of Its Motion for Summary Judgment of Invalidity of Claims 1 and 2 of U.S. Patent 6,113,944
CU	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibits to Torpharm's Memorandum of Law In Support of Its Motion for Summary Judgment of Invalidity of Claims 1 and 2 of U.S. Patent No. 6,113,944 - INDEX
CV	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 1 – U.S. Patent 6,113,944
CW	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 2 – Complaint dated 8/26/99 in Civil Action 99-4304
CX	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 3 – Complaint dated 9/27/00 in Civil Action 00-4888
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CY	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 4 – Complaint dated 5/2/01 in Civil Action 01-2169
CZ	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 5 – U.S. Patent 4,007,196
CAA	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 6 – U.S. Patent 4,721,723
CBB	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 7 – Paroxetine Tablets – Ex Ferrosan Report (SB02001-007710 DX618), dated 4/3/80
CCC	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 8 – Paroxetine Strategy Meeting Minutes (SB02001-412721-412730 DX622), dated 9/9/80
CDD	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 9 – Paroxetine Development Meeting Minutes (SB06001-002857-002865, 002867-002872 DX623), dated 10/8/80
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	CEE	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 10 – The Synthesis of Paroxetine Hydrochloride Report (SB02001-086316-086341 DX66), dated January 14, 1981
	CFF	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 11 – U.S. Patent 4,745,122
	CGG	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 12 - SmithKline's Response to Torpharm's Local Rule 56.1(a)(3) Statement of Material Facts dated January 9, 2001
	CHH	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 13 – File History For Serial No. 08/676,331
	CII	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 14 – U.S. Patent 5,047,246
	CJJ	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 15 – Transcript of Ram D. Pathak dated September 26, 2001
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	CKK	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 16 – <u>Pharmaceutical Dosage Forms: Tablets</u> , Vol. 1, pages 64 and 148 (1980)
	CLL	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 17 – International Application WO 92/09281
	CMM	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 18 – U.S. Patent 6,113,944 Prosecution History
	CNN	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 19 – U.S. Patent 6,113,944 Certificate of Correction dated September 6, 2000
	COO	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 20 – Decision in Canadian Litigation, SmithKline v. Apotex, dated July 6, 2001
	CPP	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 21 – U.S. Patent 4,804,669
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	CQQ	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 22 – Paxil® Package Insert, Physicians' Desk Reference, 48th Edition, pages 2267 – 2270 (1994)
	CRR	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 23 – U.S. Patent 5,340,810
	CSS	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 24 – <u>The Theory and Practice of Industrial Pharmacy</u> , pages 305, 318, 319 and 320
	CTT	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 25 – U.S. Patent 5,071,854
	CUU	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 26 – U.S. Patent 5,229,407
	CVV	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 27 – U.S. Patent 6,077,535
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	CWW	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania - Order
	CXX	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania - SmithKline Beecham Corporation and SmithKline Beecham plc's Memorandum In Opposition to Torpharm's Motion for Summary Judgment of Invalidity of Claims 1 and 2 of U.S. Patent 6,113,944
	CYY	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania - SmithKline Beecham Corporation and SmithKline Beecham plc's Memorandum In Opposition to Torpharm's Motion for Summary Judgment of Invalidity of Claims 1 and 2 of U.S. Patent 6,113,944 - INDEX
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CZZ	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 1 – Affidavit of Richard Killworth, and Exhibits A-B Attached Thereto (Exhibit A – Richard Killworth's Curriculum Vitae; Exhibit B – Manual of Patent Examining Procedures, pages 700-19 to 700-21; 1800-82 to 1800-83; 1800-145; 2100-68 to 2100-112; and 2100-194)
CAAA	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 2 – Affidavit of Dr. Christopher T. Rhodes and Exhibits A-I Attached Thereto (Exhibit A – Christopher Rhodes' Curriculum Vitae; Exhibit B – <u>Drug Stability Principles and Practices</u> , Vol. 107, page 6 and page 113; Exhibit C – <u>Pharmaceutics of Solids and Solid Dosage Forms</u> , pages 147, 148, 149 and 161; Exhibit D – <u>Pharmaceutical Dosage Forms</u> , Volume I, pages 195-199; Exhibit E – <u>Canadian Journal of Pharmaceutical Sciences</u> , Vol. 8, No. 1, pages 1-5 (1973); Exhibit F – <u>Modern Pharmaceutics</u> , Second Edition, page 372; Exhibit G – European Patent Application 0 188 081; Exhibit H – European Patent Application 0 269 303; Exhibit I – <u>Pharmaceutical Development and Technology</u> , 7(1), pages 1-32 (2002))
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CBBB	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 3 – Affidavit of Dr. Robin Roman and Exhibits A-D Attached Thereto (Exhibit A – Robin Roman's Curriculum Vitae; Exhibit B – SmithKline Beecham Pharmaceuticals Department Report No. 93GBPT03_1; Exhibit C – Memo to D. J. White from D. G. Doughty regarding Paroxetine Pink Tablets, dated January 18, 1993; Exhibit D – Memo to D. Monkhouse from R. Roman regarding Paroxetine 20 mg Tablets Batch G91027, dated November 19, 1991)
CCCC	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 4 – Affidavit of James Mills and Exhibit Attached Thereto (Notice of Allegation to SmithKline Beecham Pharma from Apotex, Inc. dated March 1, 1999)
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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CDDD	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 5 – Affidavit of Sanya Sukduang and Exhibits A-G Attached Thereto (Exhibit A – In Civil Action No. 1:00 CV 01179 a Joint Stipulated Protective Order Pursuant to Rule 26c, dated May 18, 2001; Exhibit B – Letter from Kenneth Curtis to Mark Waddell re: SB et al. v. Synthon Pharmaceuticals Ltd, et al., dated March 15, 2002; Exhibit C – In U.S. District Court in the Southern District of New York – Subpoena in a Civil Case dated 3/13/02; Exhibit D – Letter to Kenneth Curtis from Mark Waddell re: SB et al v. Synthon Pharmaceuticals Ltd, et al., dated March 25, 2002; Exhibit E – In U.S. District Court in the Southern District of New York – Chadbourne and Parke LLP's Objections to Subpoena, dated March 25, 2002; Exhibit F – Letter from Kenneth Curtis to Mark Waddell re: SB et al. v. Apotex Corporation et al., dated March 29, 2002; Exhibit G – In U.S. District Court for the Middle District of North Carolina – Plaintiffs' Motion to Amend Joint Stipulated Protective Order Pursuant to Rule 26(c), dated April 5, 2002)
CEEE	Consolidated Civil Action Nos. 99-CV-4303, 00-CV-4888, 01-CV-159 and 01-CV-2169 in the U.S. District Court for Eastern District of Pennsylvania – Exhibit 6 – Copy of the Northern District of Illinois Memorandum and Order Dated January 14, 2002, in SmithKline Beecham Corporations v. Pentech Pharmaceuticals, Inc. Civil Action No. 00C2855
EXAMINER	
DATE CONSIDERED	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	